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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,075	03/30/2004	Yoshinori Sekiguchi	Q74855	3021

23373 7590 07/16/2007  
SUGHRUE MION, PLLC  
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SUITE 800  
WASHINGTON, DC 20037

EXAMINER
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JAISLE, CECILIA M

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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07/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/812,075	Applicant(s) SEKIGUCHI ET AL.	
	Examiner Cecilia M. Jaisle	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on Oct. 23, 2006 & Mar. 13, 2007.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) 3-56, 59-62, 65-67, 69-71, 73, 74, 102 & 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 57, 58, 63, 64, 68, 72, 75-101, 103 and 107-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>May 4, 2007 &amp; Jun. 1, 2007</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED OFFICE ACTION****Election/Restriction**

Applicant's election of Group III, Claims 1, 2, 57, 58, 63, 64, 68, 72, 75-101, 103 and 107-112 (in part), drawn to compounds of formula I wherein Q is formula IV (pyrimidine), and pharmaceutical compositions thereof, classified in classes 514 and 544, various subclasses depending on substituents, in the reply filed on Oct. 23, 2006 is acknowledged. Applicant's further election of the species of Example 3398, 3-chloro-N-[cis-4-(4-dimethylamino-5-methyl-pyrimidin-2-ylamino)-cyclohexyl]-4-fluoro-benzamide methanesulfonic acid, in the further reply filed on Mar. 13, 2007 is also acknowledged. Claims 1, 2, 57, 58, 63, 64, 68, 72, 75-101, 103 and 107-112 read on the elected species, and these claims are under examination only to the extent that they are patentably indistinct from the elected species. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 3-56, 59-62, 65-67, 69-71, 73, 74, 102 and 104-106 are withdrawn as non-elected.

***Rejection Under 35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 2, 57, 58, 63, 64, 68, 72, 75-101, 103 and 107-112 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutically salts, does not reasonably provide enablement for hydrates and solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims, insofar as they embrace hydrates and solvates are not enabled. Although hydrates and solvates are prophesied, there is not a single example presented of the production of a hydrate or a solvate. The evidence of the specification is thus clear: These compounds do not possess the property of forming hydrates or solvates; there is no evidence that such compounds even exist. Thus, this is a circumstance where the "specification is evidence of its own inadequacy" (*In re Rainer*, 153 USPQ 802, 807). These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190:

The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist ... the examples of the '881 patent do not produce the postulated compounds ... there is ... no evidence that such compounds even exist.

This circumstance appears true here: no evidence shows that hydrates or solvates of these compounds actually exist; if they did, they would have formed. Applicants must show that hydrates and solvates can be made, or limit the claims accordingly.

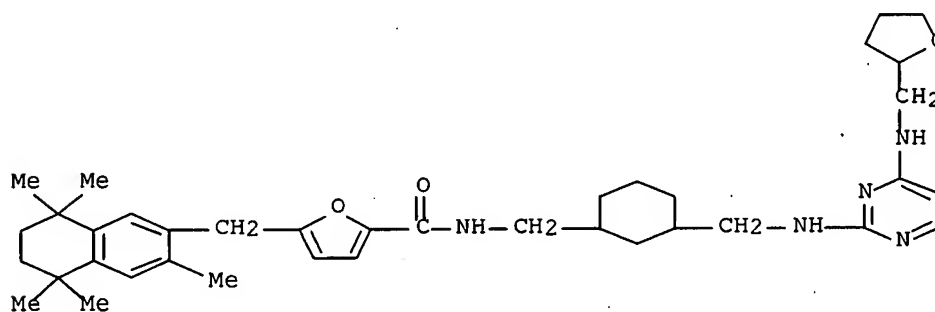
**Rejections Under 35 US 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 75, 79, 90, 94, 98, 100, 103, 107 and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson, et al., US Pat. No. 7,101,878, available as a reference as of the publication date of WO2000/020358A2, published Apr 13, 2000, describing (paragraph [0032]) RN 263847-63-8, 2-Furancarboxamide, N-[[[3-[[[4-[[[(tetrahydro-2-furanyl)methyl]amino]-2-pyrimidinyl]amino]methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,

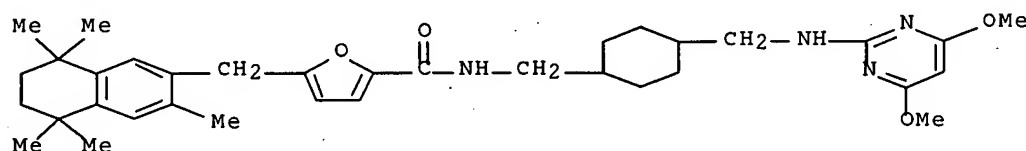


, wherein Q in

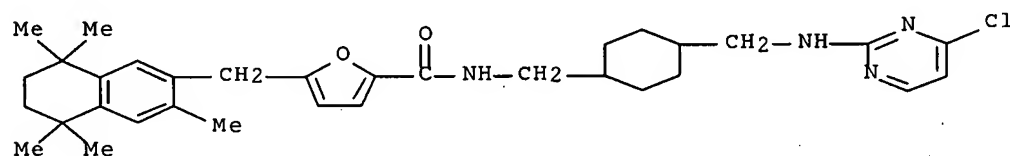
claimed Formula (I) is 2-pyrimidinyl, R2 is tetrahydro-2-furanyl-methylamino, p is 0 so that T is absent, L is Formula (VI), A and B are each -CH2-, Y is -C(O)-, and R1 is (viii) heterocyclyl substituted by methyl substituted by carbocyclic aryl,

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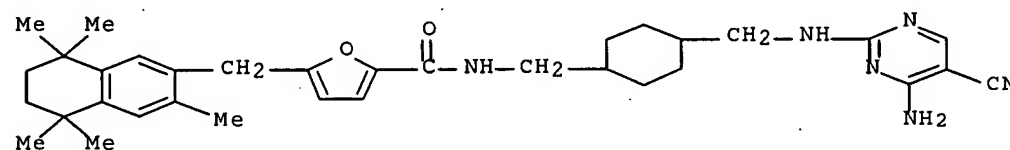
RN 263848-23-3, 2-Furancarboxamide, N-[[4-[(4,6-dimethoxy-2-pyrimidinyl)amino]methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,



RN 263848-45-9, 2-Furancarboxamide, N-[[4-[(4-chloro-2-pyrimidinyl)amino]methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,

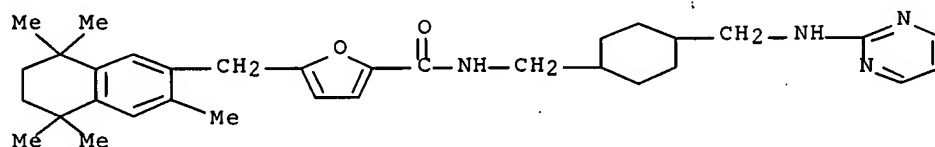


RN 263848-46-0, 2-Furancarboxamide, N-[[4-[(4-amino-5-cyano-2-pyrimidinyl)amino]methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,

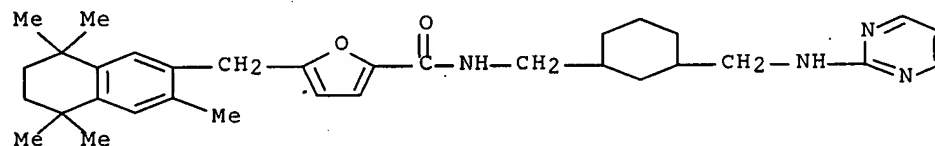


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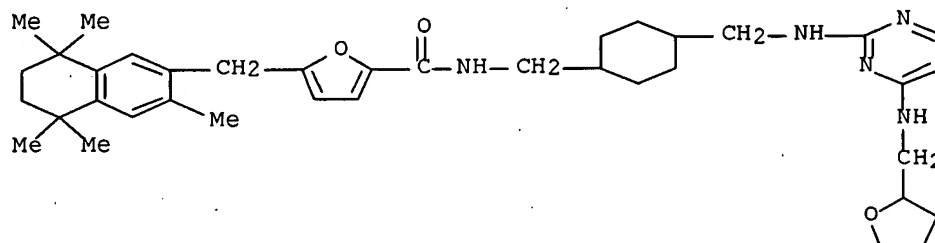
RN 263848-62-0, 2-Furancarboxamide, N-[[4-[(2-pyrimidinylamino)methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,



RN 263848-88-0, 2-Furancarboxamide, N-[[3-[(2-pyrimidinylamino)methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,

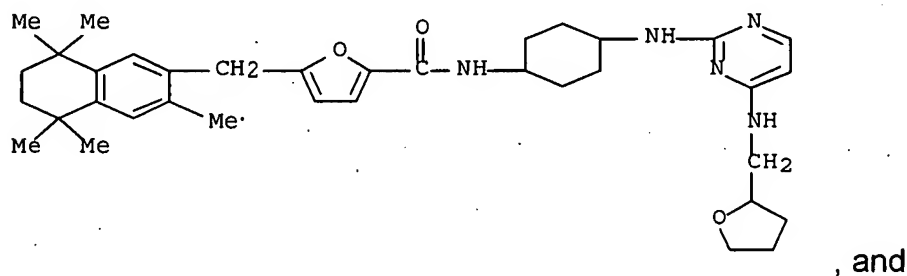


RN 263848-44-8, 2-Furancarboxamide, N-[[4-[[[4-[(tetrahydro-2-furanyl)methyl]amino]-2-pyrimidinyl]amino]methyl]cyclohexyl]methyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,

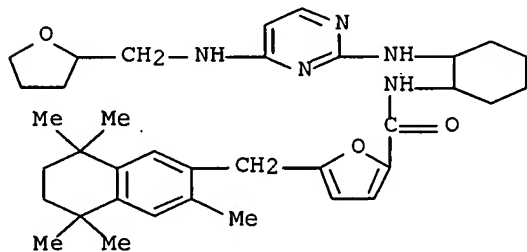


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RN 263849-03-2, 2-Furancarboxamide, N-[4-[[4-[[[(tetrahydro-2-furanyl)methyl]amino]-2-pyrimidinyl]amino]cyclohexyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,



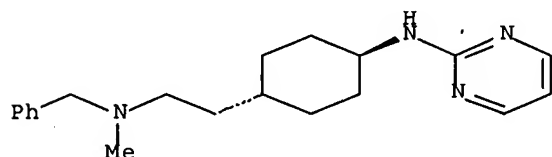
RN 263851-05-4, 2-Furancarboxamide, N-[2-[[4-[[[(tetrahydro-2-furanyl)methyl]amino]-2-pyrimidinyl]amino]cyclohexyl]-5-[(5,6,7,8-tetrahydro-3,5,5,8,8-pentamethyl-2-naphthalenyl)methyl]-,



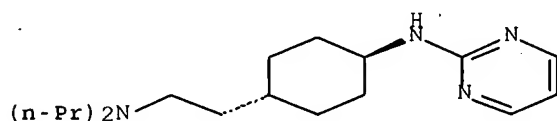
Claims 1, 2, 75-77, 79, 82-85, 88-90, 93, 94, 98, 100, 103, 107 and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Wustrow, et al., Journal of Medicinal Chemistry (1998), 41(5), 760-771, describing



RN 204245-70-5, 2-Pyrimidinamine, N-[4-[2-(methyl(phenylmethyl)amino)ethyl]cyclohexyl]-, trans-,

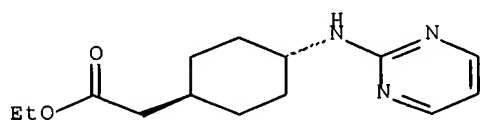


RN 204245-89-6, 2-Pyrimidinamine, N-[4-[2-(dipropylamino)ethyl]cyclohexyl]-, trans-,

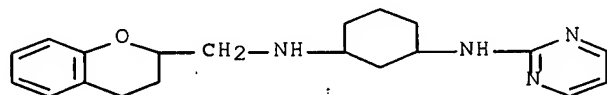


, and

RN 189153-07-9, Cyclohexanecarboxylic acid, 4-(2-pyrimidinylamino)-, ethyl ester, trans-,

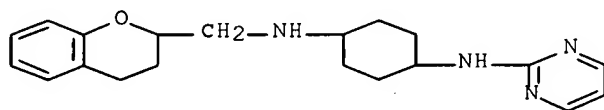


Claims 1, 2, 75, 79, 90, 94, 98, 100, 103, 107 and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Lommen, et al., US Pat. No. 5,607,949, issued Mar. 4, 1997, describing RN 155429-41-7, 1,3-Cyclohexanediamine, N-[(3,4-dihydro-2H-1-benzopyran-2-yl)methyl]-N'-2-pyrimidinyl-,

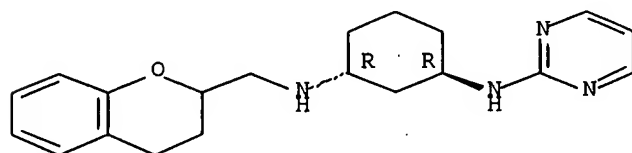


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RN 155429-48-4, 1,4-Cyclohexanediamine, N-[(3,4-dihydro-2H-1-benzopyran-2-yl)methyl]-N'-2-pyrimidinyl-,

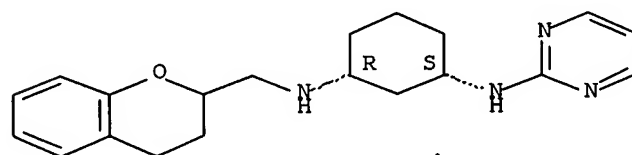


RN 155426-33-8, 1,3-Cyclohexanediamine, N-[(3,4-dihydro-2H-1-benzopyran-2-yl)methyl]-N'-2-pyrimidinyl-, dihydrochloride, trans-,



● 2 HCl

RN 155426-34-9, 1,3-Cyclohexanediamine, N-[(3,4-dihydro-2H-1-benzopyran-2-yl)methyl]-N'-2-pyrimidinyl-, dihydrochloride, cis-,

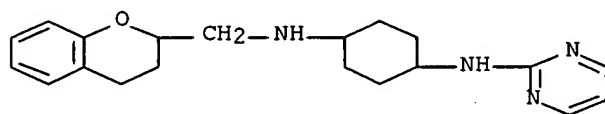


● 2 HCl

, and

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RN 155426-39-4, 1,4-Cyclohexanediamine, N-[(3,4-dihydro-2H-1-benzopyran-2-yl)methyl]-N'-2-pyrimidinyl-, dihydrochloride,



● 2 HCl

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

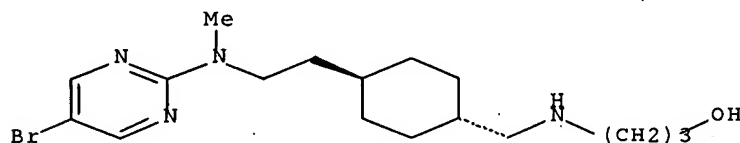
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 75, 76, 79, 82-85, 90, 94, 98, 100, 103, 107 and 112 are rejected under 35 U.S.C. 102(e) as being anticipated by Ackerman, et al., US Pat. No.

7,012,077, entitled to the filing date of Dec. 5, 2002, describes RN 553677-39-7, 1-

Propanol, 3-[[[trans-4-[2-[(5-bromo-2-pyrimidinyl)methylamino]ethyl]cyclohexyl]methyl]amino]-



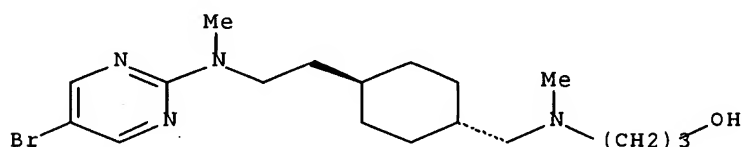
, wherein Q in claimed Formula

(I) is 2-pyrimidinyl, R<sub>2</sub> is hydrogen, p is 1, T is bromo, L is Formula (VI), A and B are

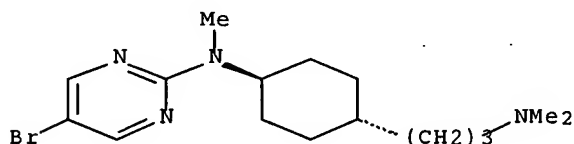
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each  $-\text{CH}_2-$ , Y is a single bond, and R1 is (i) propyl substituted by hydroxy,

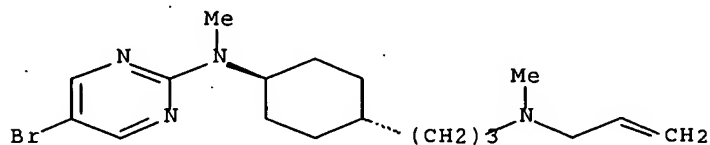
RN 553677-40-0, 1-Propanol, 3-[[[trans-4-[2-[(5-bromo-2-pyrimidinyl)methylamino]ethyl]cyclohexyl]methyl]methylamino]-,



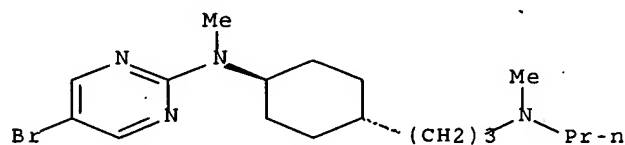
RN 553676-54-3, 2-Pyrimidinamine, 5-bromo-N-[trans-4-[3-(dimethylamino)propyl]cyclohexyl]-N-methyl-,



RN 553676-55-4, 2-Pyrimidinamine, 5-bromo-N-methyl-N-[trans-4-[3-(methyl-2-propenylamino)propyl]cyclohexyl]-,

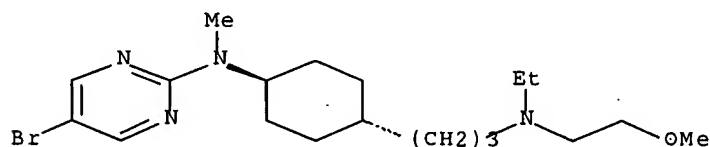


RN 553676-56-5, 2-Pyrimidinamine, 5-bromo-N-methyl-N-[trans-4-[3-(methylpropylamino)propyl]cyclohexyl]-,

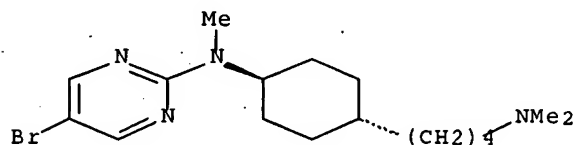


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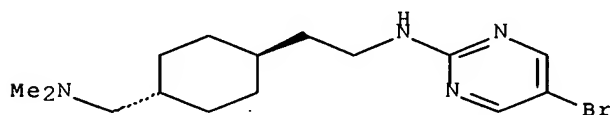
RN 553676-57-6, 2-Pyrimidinamine, 5-bromo-N-[trans-4-[3-[ethyl(2-methoxyethyl)amino]propyl]cyclohexyl]-N-methyl-,



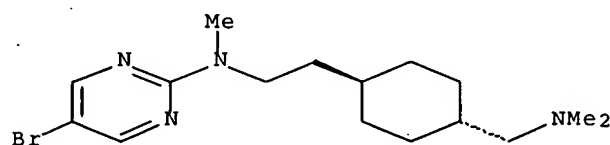
RN 553676-71-4, 2-Pyrimidinamine, 5-bromo-N-[trans-4-[4-(dimethylamino)butyl]cyclohexyl]-N-methyl-,



RN 553677-00-2, 2-Pyrimidinamine, 5-bromo-N-[2-[trans-4-(dimethylamino)methyl]cyclohexyl]ethyl]-,



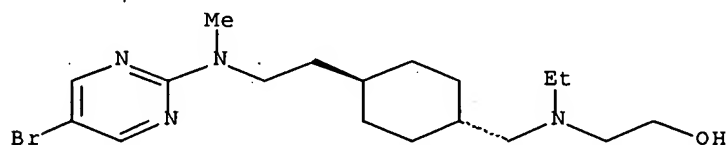
RN 553677-02-4, 2-Pyrimidinamine, 5-bromo-N-[2-[trans-4-[(dimethylamino)methyl]cyclohexyl]ethyl]-N-methyl-,



, and

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RN 553677-37-5, Ethanol, 2-[[[trans-4-[2-[(5-bromo-2-pyrimidinyl)methylamino]ethyl]cyclohexyl)methyl]ethylamino]-,



### ***Improper Markush Rejection***

Claims 1, 2, 57, 58, 63, 64, 68, 72, 75-101, 103 and 107-112 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. This does not constitute an art-recognized genus. Because of the marked structural differences at a part of the molecule essential for utility, the claims are deemed to lack unity of invention (see *In re Harnish*, 206 USPQ 300). The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter will overcome the rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J. D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle, J. D.



MARK L. BERCH  
PRIMARY EXAMINER  
GROUP 120 - ART UNIT 1624